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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,995	10/05/2001	John P. McKearn	CU-2560 RJS	4037

7590

06/13/2003

Mr. James M. Warner
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EXAMINER

PATEL, SUDHAKER B

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 06/13/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,995

Applicant(s)

J.P. McKearn et al

Examiner

SUDHAKER PATEL, D.Sc. Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 8, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 11, 21, 43-46, 54, 71, 86, 87, 107, and 108 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 11, 21, 43-46, 54, 71, 86, 87, 107, and 108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

I. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/18/03 has been entered.

Applicants' amendment paper #19 dated 4/25/03 is acknowledged.

Applicants' O.K. on 6/9/03 for deletion of prevention in claims 1,44,107,108 by examiners' amendment is appreciated, but not done so for following reasons.

Applicants' arguments and remarks have been considered, but upon further review and reconsideration, this application is found not ready for allowance at this stage for the reasons stated below:

II. Rejections withdrawn:

Applicants have provided Terminal disclaimers for U.S. Application Sr. No. 09843132 filed 4/25/2001 and also for U.S. Application Sr. No. 10150546, filed 5/16/2002. Therefore, DP rejections are now withdrawn.

III. Rejections maintained:

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IIIA.

Claim Rejections - 35 U.S.C. § 112

Claims 1-3,11,21,43-46,54,71,86,87,107,108 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a neoplasia disorder, does not reasonably provide enablement for preventing all the disorders recited herein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The reasons for rejections are the same as already outlined in earlier Office Communication paper #17 dated 11/25/02.

Following additional references are cited for applicants' quick review:

- The **definition of word “ prevent/preventing”** as recited in Webster's Dictionary, ISBN: 0-395-33957-X page 933 is: “ To **anticipate or counter in advance**”.

Applicants remain silent about methods which will allow to anticipate or counter in advance diseases as recited herein.

- **Current status for preventive measures for cancer:**

Novotny et al(PubMed Abstract 12745645, also cited as Hematology, 8/3, 129-37(Jun. 2003))-stat that:“ The current failure of preventive measures to significantly reduce the increasing incidence of these common tumors illustrates the importance of

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effective cancer treatment strategies, including chemotherapy. The combination of various anticancer drugs, given together with surgery and radiotherapy, gives hope to many patients. There has been recent evidence of improved therapeutic outcome with recent approaches and newer agents but for continuing effective chemotherapeutic treatment there is a need for a detailed understanding of their mechanisms of action and on the rationale of their application".

Statements of utility, which relate to or imply to treatment and prevention of a disease are subject to closer scrutiny. *Ex parte Moore et al* (POBA 1960) 128 USPQ 8. Claims 1-3, 11, 21, 43-46, 54, 71, 86, 87, 107, 108 do not meet the utility guidelines. The claims do not qualify as one utility statement, and are not believable on their face. Claims will require too much experimentation to determine what patient dosage relationship would produce what results. It is not believable on its face that any one compound or its composition either alone or complex would have all of the utilities as recited herein. *In re Hozumi*, 226 USPQ 353.

Evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of claims directed to a method of treating 7 types of cancer with member of a class of several compounds. *In re Buting*, (CCPA 1969) 418 F2d 540, 163 USPQ 689.

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The instant claims relate not only to treatment of a cancer of a single human body part cancer, but also to treatment and prevention of any and all neoplasia disorders as recited herein.

The facts as provided above and also in earlier Office Communications dated 7/17/02 and 11/25/02 do support the need for additional quantity of experimentation which would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan regarding the method of prevention for various disorders affecting different body parts as claimed herein.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability", etc have been demonstrated to be sufficiently lacking in the use as a method of preventing cancer(s).

When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished. In re Ferens, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, Genentech vs. Novo Nordisk, 42 USPQ 2nd 1001, 1006.

IIIB.

Claim Rejections - 35 U.S.C. § 103

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Rejection of claims 1-3,11,21,43-46,54,71,86,87,107,108 under 35 U.S.C. 103
(a) are maintained further for the reasons already provided in earlier Office
communication paper # 17 dated 11/25/02.

Examiner's position is as follows:

- ◆ Method of treating disorders by compound(s) used for compositions as claimed herein are disclosed in prior art on record by ref. Zook et al (WO 9720824). See Example 1 in page 54.
- ◆ MMP activity of the compounds for utility has been disclosed on page 4(WO 9720824) for treating cancer.
- ◆ As recited in earlier Office communication paper # 17 dated 11/25/02:" it is well known in the prior art(s) to use combinations of MMP-inhibitors together with other antineoplastic agents in the treatment of cancer(see U.S.P. 5672583; U.S.P. 5629343; WO 9748685). Moreover, anastrozole, irinotecan and topotecan are well known antineoplastic agents(Biological Abstracts, Vol.00, Philadelphia, PA,USA Abstract No. Prev 199800349798, Barni Sandro et al; Mueller-Bohn T in Deutsche Apotheker Zeitung, 137/41,54-55(1997). It can therefore not be considered as inventive to use the claimed combinations of a MMP inhibitor with anastrozole, irinotecan or topotecan, especially since no **special or unexpected effect has been shown**".

- ◆ Art Recognized Equivalence for the same Purpose:

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" It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for very same purpose...[T]he idea of combining them flows logically from their having been individually taught in the prior art". In re Kerkhoven, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). MPEP 2144.06.

Applicants have remained silent about showing these unexpected effect(s) for their claims.

IV.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel, D.Sc. Tech. whose telephone number is (703) 308 4709. The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM.


If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

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Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.


SP/6/12/03


MUKUND SHAH
SUPERVISORY PATENT EXAMINER
ART UNIT 1624
